K120752

510(k) Summary

as required by 807.92

JUN - 8 2012

1. Company Identification

Konica Minolta Medical & Graphic, Inc.
No.1 Sakura-machi, Hino-shi, Tokyo 191-8511, Japan
Establishment Registration Number: 3004485675

2. Submitter's Name and Address

Shigeyuki Kojima
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Regulations and Standards Section, Quality Assurance Center
No. 1 Sakura-machi, Hino-shi, Tokyo 191-8511, Japan
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3. Date of Submission

March 9, 2012

4. Device Trade Name

AeroDR Stitching System

5. Classification, Product Code

Class Ⅱ, 21CFR892.1680, 90 KPR

6. Predicate Device

REGIUS MODEL 170, 510(k) number K051998

7. Indications for Use

The AeroDR Stitching System is used with Konica Minolta AeroDR SYSTEM which is indicated for use in generating radiographic images of human anatomy. It is intended to replace radiographic film/screen systems in general-purpose diagnostic procedures. This device is used for examinations of long areas of anatomy such as the leg and spine. This device is not indicated for use in mammography, fluoroscopy, tomography and angiography applications.

8. Device Description

The AeroDR Stitching System is used with 510(k) cleared Konica Minolta AeroDR SYSTEM (K102349) which is indicated for use in generating radiographic images of human anatomy.

The AeroDR Stitching System is an accessory of stationary X-ray system which

extends the capability of the AeroDR SYSTEM to allow the capture of long length images with an image area up to 1196mm x 349mm. It consists of AeroDR Stitching Unit, AeroDR Stitching X-ray Auto Barrier Unit and Power Supply Unit.
The AeroDR Detecter (K102349) loaded in the AeroDR Stitching Unit takes up to 3 images and transfer them to the Console CS-7 (K102349). Combining the transferred images in the CS-7 enables diagnosis of long images.

9. Risk Analysis (Summary of Design Control Activities)

The Risk Analysis for the AeroDR Stitching System was conducted on the basis of ISO14971, "Medical devices – Application of risk management to medical devices".
As a result of risk control measures, the risk associated with all of the identified hazards was reduced to an acceptable level or ALARP (as low as reasonably practicable).

10. Compliance of Recognized Consensus Standard

In terms of Indications for use of this AeroDR Stitching System, it has been tested and shown to meet the requirements of IEC 60601-1 and IEC 60601-1-2 as follows.
Safety standard: IEC60601-1 Ed.2 (1988) + A1 (1991)+A2(1995)
Electromagnetic Compatibility: IEC60601-1-2 Ed.3(2007)

11. Substantial Equivalence to Predicate Device

The predicate device is our REGIUS MODEL 170, 510(k) number K051998.
Both AeroDR Stitching System and the predicate are used for examinations of long areas of anatomy such as the leg and spine.
Comparison of the principal characteristics of these devices, please refer to the Substantial Equivalence Comparison Table as follows.

AeroDR Stitching System Substantial Equivalence Comparison Table

	Cleared Medical Device	Medical Device Applied for Clearance
Applicant, etc.	Company : KonicaMinolta Medical &Graphic, Inc. Product Name : REGIUS MODEL 170 CR cassette:RC-110T/RC-110R K Number : K051198	Company: KonicaMinolta Medical &Graphic, Inc. Product Name: AeroDR Stitching System
Configuration	The REGIUS MODEL 170 is an X-ray image reader which uses a stimulable phosphor plate (Plate) as X-ray detector installed in a separate cassette.	The AeroDR Stitching System is used with 510(k) cleared Konica Minolta AeroDR SYSTEM (K102349). The AeroDR Stitching System extends the

	The REGIUS MODEL 170 consists of REGIUS MODEL 170 image reader and CR Cassette / Plate. It reads the image recorded on the Plate and transfers the image data to an externally connected device such as Console CS3000 (K051523). Using the CR cassette with multiple (three) stimulable phosphor plates aligned along the long side, latent images are produced, and the visual image is generated by scanning with a separate reader device. Combining the transferred images in the CS3000 enables diagnosis of long images.	capability of the AeroDR SYSTEM to allow the capture of long length images. AeroDR Stitching System consists of AeroDR Stitching Unit, AeroDR Stitching X-ray Auto Barrier Unit and Power Supply Unit. The AeroDR Detecter (K102349) loaded in the AeroDR Stitching Unit takes up to three images and transfers them to the Console CS-7 (K102349). Combining the transferred images in the CS-7 enables diagnosis of long images.
Principle of Operation	Using the CR cassette with multiple stimulable phosphor plates aligned along the long side, position the cassette at the back of the patient and make a single X-ray exposure over the necessary area. Reload the exposed image into the other cassettes, and feed these cassettes into the reader device in order so that the image is independently scanned and multiple images are stitched and displayed on the console by the image processing.	Position the AeroDR Stitching unit at the back of the patient. The AeroDR Stitching System produces long length images of subjects by moving a 14 x 17 inch AeroDR Detector up and down inside the AeroDR Stitching Unit and takes up to 3 images. Transfer these multiple images to the Console CS-7 (K102349) and stitch multiple images by image processing on the console.
Specifications	REGIUS MODEL 170 CR cassette:RC-110T 1) Vertical Exposure range 14×42inch (14×14×3plates) 11×24inch (11×12×2plates) 10×36inch (10×12×3plates) 14×51inch (14×17×3plates) 2) Sampling Pitch : 87.5/175μm 3)Operation Environment Temperature : 15～30 C Humidity : 30～80%RH	AeroDR Detector (K102349) : 14×17inch FPD Pixel Size: 175μ) AeroDR Stitching System (Device) 1) Vertical Exposure range SID=2.4m : Max. 50"(3shoots) SID=2.0m : Max. 41"(2shoots) SID=1.5m : Max. 31"(2shoots) Width 14inch only 2)Operation Environment Temperature : 15～30 C Humidity : 30～80%RH
Indications for Use	The Direct Digitizer, REGIUS MODEL 170 is an X-ray image reader which uses a stimulable phosphor plate (Plate) as X-ray detector installed in a separate cassette. It	The AeroDR Stitching System is used with Konica Minolta AeroDR SYSTEM which is indicated for use in generating radiographic images of human anatomy. It is intended to

	reads the image recorded on the Plate and transfers the image data to an externally connected device such as a host computer, an order input device, an image display device, a printer, an image data filing device, and other image reproduction devices. REGIUS MODEL 170 is used to obtain image data of long areas of anatomy such as the whole spine or the whole lower leg. REGIUS MODEL 170 is also used to obtain image data to verify the position for a radiotherapy location. It is designed intended to use in a clinic, a radiology department in a hospital and in other medical facilities. It is not intended for use with digital mammography system.	replace radiographic film/screen systems in general-purpose diagnostic procedures. This device is used for examinations of long areas of anatomy such as the leg and spine. This device is not indicated for use in mammography, fluoroscopy, tomography and angiography applications.

12. Performance-Testing

Performance testing was conducted to verify the design output met the design input requirements and to validate AeroDR Stitching SYSTEM conformed to the defined user needs and intended uses upon the quality of the device software. Through validation results of sample images and non-clinical testing under simulated use conditions, safe, effectiveness and performances are confirmed the achievement of predefined acceptance criteria, as well as substantially equivalence to the predicate device, besides product safety and electromagnetic compatibility.

13. Conclusion

Comprehensively, we judged that the AeroDR Stitching System has the same technological characteristics as the predicate devices. This 510(k) has demonstrated substantial equivalence as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Konica Minolta Medical & Graphic, Inc.
% Mr. Russel Munves
Official Correspondent
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140 East 45th Street, 25th Floor
Two Grand General Tower
NEW YORK NY 10017

JUN - 8 2012

Re: K120752
Trade/Device Name: AeroDR Stitching System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: May 22, 2012
Received: May 23, 2012

Dear Mr. Munves:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) : K120752

Device Name : AeroDR Stitching System

Indications for Use:

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-off
Office of In Vitro Diagnostic Devices
Evaluation and Safety

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